510(k) Traditional
Meisinger Dental Bone Screw K132212

FEB 14 2014

Section #5

510(k) Summary

1. Applicant's Name and Address

Hager & Meisinger GmbH
Hansemannstraße 10
41468 Neuss, Germany
Phone: (0049) 2131 2012-0
Fax: (0049) 2131 2012- 222
Contact Person: Wiebke Stolten
Management product approval and product validation (Regulatory Affairs)

2. Date Prepared

Date prepared: 10/22/2013

3. Name of the device

Trade Name:	Meisinger Screw System TX, Screw System Professional
Common Name:	Dental Bone Screws
Classification Name:	Screw, Fixation, Intraosseous
Product Code:	DZL
Regulation No:	872.4880
Class:	II
Panel:	Dental

4. Predicate Devices:

K051871 - Storz am Markt	Bone Screws
K041887 - Synthes	Craniofacial Screws

5. Device Description:

The Meisinger Dental Bone Screws consist of Titanium alloy Grade 5 with 1.1mm, 1.3mm and 1.5mm diameter and with lengths between 7mm – 16mm.

Section #5

510(k) Summary

The bone screws have a self-tapping design and the connection between screw and screw driver is realized by a socket head or a hexalobular connection to obtain a clamping force.
Dental Bone Screws are delivered non sterile.

6. Intended Use:

The Meisinger Dental Bone Screws are intended for fixation of bone segments e.g. for horizontal or vertical augmentative grafts. Depending on indication the user choose the matching screw, prepares the pit hole and inserts the screw.
The screws are intended for single use only.

7. Performance tests and used standards / Clinical data

The following standards have been followed for the development, production, performance and safety testing of Dental Bone Screws: AAMI ST79, ISO 17664, ISO 11607-1, ISO 2832-3, ASTM F136, ISO 14971, ISO 10993-1, ISO 10993-5, ISO 17665-1, ASTM F543.
A performance test has been performed with the result that the design and function are equivalent to the predicted devices.
Clinical data and conclusions were not needed for this device.

8. Basis for substantial equivalence

The Meisinger Dental Bone Screws have the same intended use and are substantially equivalent to the legally marketed predicate devices in the United States.
The screws use the same biocompatible materials meeting the requirements from ASTM F136 as the predicated devices. The design is similar, at least equivalent to predicated devices: All products have comparable dimensions and design and the intended use is equivalent. The function and intended use, material, possible product have been evaluated as acceptable and equivalent to predicated devices.

Based on the information provided in the summary we conclude that the Meisinger Dental Bone Screws are substantially equivalent to the legally marketed predicate devices described.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

February 14, 2014

Hager & Meisinger Gmbh
Ms.Wiebke Stolten
Regulatory Affairs
Hansemannstrasse 10
Neuss, D-41468 Germany

Re: K132212
Trade/Device Name: Meisinger Screw System TX, Screw System Professional
Regulation Number: 21 CFR 872.4880
Regulation Name: Bone Screw
Regulatory Class: Class II
Product Code: DZL
Dated: November 13, 2013
Received: November19, 2013

Dear Ms. Stolten:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

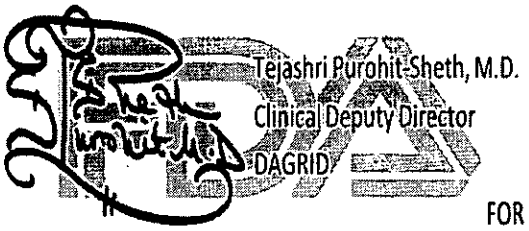
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



FOR

Erin I. Keith, M.S.
Acting Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Traditional
Meisinger Dental Bone Screws

Section #4

Indications for Use Statement

510(k) Number (if known): K132212

Device Name: Dental Bone Screws

Indications for use:

The Meisinger Dental Bone Screws are intended for fixation of bone segments e.g. for horizontal or vertical augmentative grafts. Depending on indication the user choose the matching screw, prepares the pit hole and inserts the screw.

The screws are intended for single use only.

Prescription Use X	AND/OR	Over-The-Counter Use ___
(Part 21 CFR 801 Subpart D)		(Part 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Mary S. Runner -S
2014.02.14
15:42:03 -05'00'